

## Effectiveness Bulletin

# Developing and implementing clinical practice guidelines

Jeremy Grimshaw, Nick Freemantle, Sheila Wallace, Ian Russell, Brian Hurwitz, Ian Watt, Andrew Long, Trevor Sheldon

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The *Effective Health Care* bulletins have concentrated on providing systematic reviews of the research evidence on clinical and cost effectiveness to help inform decision makers and clinicians in the NHS. However, providing information by itself is rarely sufficient to stimulate corresponding change in practice. Various implementation strategies can be used to promote the use of research evidence. One approach which has received growing attention and support is the development and implementation of clinical practice guidelines.<sup>1,2</sup> These are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."<sup>3</sup> Some previous bulletins argued for the incorporation of the evidence on effectiveness into guidelines,<sup>4,5</sup> and it has been argued that healthcare commissioners should purchase guidelines or protocols rather than simple procedures.<sup>6</sup>

This paper examines the evidence on whether practice guidelines can change the behaviour of health professionals and how best to introduce them into clinical practice. The characteristics of high quality guidelines and how purchasers might use guidelines in commissioning are also considered.

### Evaluating implementation of guidelines

Grimshaw and Russell undertook a systematic review of rigorous evaluations of clinical guidelines published between 1976 and 1992.<sup>7</sup> In this paper the review has been updated to include another 32 studies either previously unidentified or published up until June 1994. To identify evaluations of clinical guidelines the DHSS-DATA,<sup>8</sup> Embase,<sup>9</sup> Medline,<sup>10</sup> and SIGLE<sup>11</sup> databases were searched, all since 1975; published bibliographies of related topics<sup>12-26</sup> were searched; and citations in articles were reviewed. Further references were provided by colleagues. Investigations of clinical guidelines were reviewed in depth if they were intended primarily for medical staff, if they used rigorous study designs to evaluate the effectiveness of guidelines in terms of the process of care or outcome for patients, and if they reported sufficient data for statistical analysis.

Evaluations were grouped according to a hierarchy of study designs which reflects the reliability with which they are likely to

assess implementation of guidelines (table). Generally, randomised controlled trials provide the best evidence of the effectiveness of implementation. However, in behavioural research simple randomised control trials may be more susceptible to a range of biases than in other types of research.<sup>27,28</sup> One of the most reliable trial designs for these types of interventions is one in which each participating doctor simultaneously experiences both guidelines for some conditions and the status quo for others in a balanced incomplete block design (for example, Norton and Dempsey<sup>29</sup>). Although less reliable, randomised controlled trials randomising doctors either individually or in groups and randomised controlled crossover trials (for example, Landgren *et al*<sup>30</sup>) are, with the balanced incomplete block design, considered to provide the most reliable (grade I) evidence. Before and after studies with non-randomised controls, which compare changes in the targeted behaviour with a control group of activities performed by the same doctors but not targeted by guidelines (for example, De Vos Meiring and Wells<sup>31</sup>) may provide useful though less reliable results. These studies and simple randomised controlled trials in which patients are randomised are considered together as providing grade II evidence. Time series techniques have been used to analyse before and after studies (for example, Koseoff *et al*<sup>32</sup>). Before and after studies controlled by data from other sites where non-randomised controls are selected in the belief that they may experience changes similar to those of the study populations (for example, Thompson *et al*<sup>33</sup>) can also be useful. Studies with this design were included if control and study sites were apparently similar; baseline characteristics and performance in control and study sites were similar; and data collection was contemporaneous in study and control sites during both phases of the study. These two designs are considered to provide grade III evidence. Simple uncontrolled before and after studies were not reviewed as secular trends or sudden changes make it impossible to attribute observed changes to the intervention.

### Do guidelines influence clinical practice?

In all, we identified 91 studies which fulfilled the stated criteria, covering a wide range of

**Health Services Research Unit, University of Aberdeen, Aberdeen AB9 2ZD**  
Jeremy Grimshaw, programme director  
Sheila Wallace, research fellow

**NHS Centre for Reviews and Dissemination, University of York, York YO1 5DD**  
Nick Freemantle, research fellow  
Ian Watt, clinical liaison officer  
Trevor Sheldon, director

**Department of Health Sciences, University of York, York YO1 5DD**  
Ian Russell, professor of health sciences

**Department of Primary Health Care, University College, London WC1E 6AU**  
Brian Hurwitz, senior lecturer

**Nuffield Institute for Health, University of Leeds, Leeds LS2 9PL**  
Andrew Long, senior lecturer

Correspondence to:  
Dr J Grimshaw,  
Health Services Research Unit, University of Aberdeen, Drew Kay Wing, Polwarth Building, Foresterhill, Aberdeen AB9 2ZD

## Evidence of effectiveness of guidelines from rigorous studies of introducing guidelines

Authors	Setting	Clinical area	End user involvement in guideline development?	Interventions to promote use of guidelines	Design of trial or study	Effect on process	Effect on outcome
<i>Studies of clinical care</i>							
<i>Grade I evidence: Balanced incomplete block designs, randomised controlled trials randomising doctors, and crossover trials</i>							
McDonald 1976 <sup>14</sup>	US ambulatory care	Various medical conditions	No	Local guidelines implemented by computer generated reminders	Crossover	+++	
Sanazaro and Worth 1978 <sup>15</sup>	US hospital care	1 Paediatric, 2 surgical, and 4 medical conditions	No	National guidelines approved by local staff and placed in patients' notes	RCT-Dr	+	0
Hopkins <i>et al</i> 1980 <sup>16</sup>	US emergency room care	Hypotensive shock	No	Local guidelines distributed by brief educational programme and implemented by general reminders	RCT-Dr	++++	++
Linn 1980 <sup>17</sup>	US hospital care	Management of burns	No	National guidelines distributed by specific educational programme and implemented by general reminders	RCT-Dr	+	++
McDonald <i>et al</i> 1980 <sup>18</sup>	US ambulatory care	Various medical conditions	No	Local guidelines implemented by computer generated reminders supported by bibliographic citations on request	Crossover	++	
Sommers <i>et al</i> 1984 <sup>19</sup>	US ambulatory care	Unexplained anaemia	(i) Yes (ii) No	Guidelines implemented by aggregated feedback: (i) developed by end users (ii) developed without end users	RCT-Dr	(i) 0 (ii) ++	
Norton and Dempsey 1985 <sup>20</sup>	Canadian general practice	Cystitis and vaginitis	Yes	Guidelines implemented by aggregated feedback on baseline compliance	BIB	+++	
Palmer <i>et al</i> 1985 <sup>20</sup>	US ambulatory care	4 Medical and 4 paediatric conditions	Yes	Guidelines implemented with aggregated feedback on baseline compliance	BIB	++	
Putnam and Curry 1985 <sup>21</sup>	Canadian general practice	5 Medical conditions	(i) Yes (ii) No	Guidelines distributed by mail and personal educational package, and implemented with aggregated feedback on baseline compliance: (i) developed by end users for 2 conditions (ii) developed without end users for 2 conditions	RCT-Dr	(i) ++++ (ii) +++	
Winickoff <i>et al</i> 1985 <sup>22</sup>	US ambulatory care	Hypertension	No	National guidelines modified locally and implemented with patient specific feedback outwith the consultation and physician specific feedback	RCT-Dr	+	0
McAlister <i>et al</i> 1986 <sup>23</sup>	Canadian general practice	Hypertension	No	Provincial guidelines distributed by mail and implemented with computer generated patient specific feedback	RCT-Dr	0	++
Wirtschafter <i>et al</i> 1986 <sup>24</sup>	US community hospitals	Neonatal respiratory distress syndrome	No	Local guidelines: (i) distributed by specific educational programme (ii) (i) plus implemented with guidelines embedded in paper medical record	RCT-Dr	(i) 0 (ii) +	
Vinacor <i>et al</i> 1987 <sup>25</sup>	US ambulatory care	Diabetes mellitus	No	Local guidelines: (i) distributed by individual patient education (ii) distributed by intensive physician education and implemented by aggregated feedback, hotline to diabetic specialists, and computer generated reminder (iii) (i) + (ii)	RCT-Dr	—	(i) + (ii) + (iii) ++
Putnam and Curry 1989 <sup>26</sup>	Canadian general practice	Hypertension	(i) Yes (ii) No	(i) guidelines developed with end users (ii) guidelines developed without end users, distributed by targeted mailing	RCT-Dr	—	(i) 0 (ii) 0
Mazzuca <i>et al</i> 1990 <sup>27</sup>	US ambulatory care	Diabetes mellitus	No	Local guidelines distributed by seminar and implemented by: (i) computer generated reminder (ii) (i) + clinical materials (iii) (ii) + diabetes patient education service	RCT-Dr	(i) + (ii) + (iii) +	
Lomas <i>et al</i> 1991 <sup>28</sup>	Canadian obstetric care	Caesarean section	No	Provincial consensus development conference guidelines distributed by mailing to targeted clinicians and implemented by: (i) aggregated feedback (ii) local opinion leader	RCT-Dr	(i) 0 (ii) ++	
Margolis <i>et al</i> 1992 <sup>29</sup>	Israeli paediatric care	3 Paediatric conditions	No	Local guidelines implemented by computerised protocol	PBIB	+++	
North of England Study of Standards and Performance in General Practice 1992 <sup>30</sup>	UK general practice	5 Paediatric conditions	(i) Yes (ii) No	Guidelines implemented by feedback on baseline compliance: (i) guidelines developed by end users (ii) guidelines developed without end users	BIB	(i) + (ii) 0	(i) ++++ (ii) 0
Emslie <i>et al</i> 1993 <sup>31</sup>	UK general practice	Infertility	Yes	Guidelines distributed by mail and implemented with guidelines embedded in paper medical record	RCT-Dr	++++	
Jones <i>et al</i> 1993 <sup>32</sup>	UK general practice	Dyspepsia	Yes	Guidelines distributed by targeted mailing and implemented by a general reminder of the guidelines	RCT-Dr	++	
Soumerai <i>et al</i> 1993 <sup>33</sup>	US hospital care	Blood transfusion	No	Local guidelines distributed by lecture, printed materials, and educational outreach visits to individual doctors	RCT-Dr	+++	

<i>Authors</i>	<i>Setting</i>	<i>Clinical area</i>	<i>End user involvement in guideline development?</i>	<i>Interventions to promote use of guidelines</i>	<i>Design of trial or study</i>	<i>Effect on process</i>	<i>Effect on outcome</i>
Anderson <i>et al</i> 1994 <sup>54</sup>	US hospital care	Prevention of deep vein thrombosis	No	NIH consensus development conference national guidelines: (i) distributed by continuing medical education (ii) distributed by continuing medical education and implemented by quality assurance programme	RCT-Dr	(i) +++ (ii) +++	–
<i>Grade II evidence: randomised controlled trial randomising patients, and before and after studies controlled by activity not targeted by guidelines</i>							
McDonald 1976 <sup>55</sup>	US ambulatory care	Diabetes and other medical conditions	No	Local guidelines implemented by computer generated reminders	RCT-Pt	+++	–
Coe <i>et al</i> 1977 <sup>56</sup>	US ambulatory care	Hypertension	Yes	Guidelines implemented by computer generated reminders	RCT-Pt	–	0
Restuccia 1982 <sup>57</sup>	US hospital care	General medical conditions	No	National guidelines implemented by nurse coordinator providing: (i) direct feedback to attending physician (ii) feedback to physician adviser (iii) feedback at nurse's discretion	RCT-Pt	–	(i) ++ (ii) 0 (iii) ++
Rogers <i>et al</i> 1982 <sup>58</sup>	US ambulatory care	Hypertension, obesity, and renal disease	Yes	Local guidelines implemented by computer generated reminders	RCT-Pt	+	++
Barnett <i>et al</i> 1983 <sup>59</sup>	US ambulatory care	Hypertension	No	Local guidelines implemented by computer generated patient specific feedback	RCT-Pt	++++	++
Thomas <i>et al</i> 1983 <sup>60</sup>	US ambulatory care	Diabetes	No	Local guidelines implemented by computer generated reminders	RCT-Pt	++	0
Brownbridge <i>et al</i> 1986 <sup>61</sup>	UK general practice	Hypertension	Yes	Local guidelines discussed with participants and implemented by paper based or computerised protocol	CBA-A	++	–
Weingarten <i>et al</i> 1990 <sup>62</sup>	US hospital care	Chest pain	No	Local guidelines implemented with patient specific reminder	RCT-Pt	0	+++++
<i>Grade III evidence: before and after studies controlled by site and time series analyses</i>							
Barnett <i>et al</i> 1978 <sup>63</sup>	US ambulatory care	Streptococcal sore throat	Yes	Local guidelines "determined" by clinic staff and implemented by patient specific feedback	TSA	++	–
Kosecoff <i>et al</i> 1987 <sup>32</sup>	US hospital care	Breast cancer, caesarean section, coronary artery bypass grafting	No	NIH consensus development conference guidelines distributed by publication in professional journals, no further attempt at implementation	TSA	0	–
Lomas <i>et al</i> 1989 <sup>64</sup>	Canadian obstetric care	Caesarean section	No	Provincial consensus development conference guidelines distributed by publication in professional journals and mailing to targeted clinicians, no further attempt at implementation	TSA	+	–
Durand-Zaleski <i>et al</i> 1992 <sup>65</sup>	French hospital care	Hypovolaemia	No	National consensus development conference guidelines distributed by specific educational meetings and implemented with monthly feedback and discussion of compliance	TSA	++++	–
Sherman <i>et al</i> 1992 <sup>66</sup>	US hospital care	Localised prostatic carcinoma	No	NIH consensus development conference guidelines distributed by publication in professional journals and mailing to targeted clinicians, no further attempt at implementation	TSA	0	–
<i>Studies of preventive care</i>							
<i>Grade I evidence: Balanced incomplete block designs, randomised controlled trials randomising doctors, and crossover trials</i>							
Cohen <i>et al</i> 1982 <sup>67</sup>	US ambulatory care	8 Preventive tasks	No	Local guidelines distributed by intensive educational intervention and placed in patients' notes	RCT-Dr	++++	–
McDonald <i>et al</i> 1984, 1992 <sup>68 69</sup>	US ambulatory care	9 Preventive tasks and 6 laboratory tests	No	Local guidelines implemented by computer generated reminders	RCT-Dr	+++	++
Winickoff <i>et al</i> 1984 <sup>70</sup>	US community health plan	Colorectal cancer screening	Yes	Local guidelines distributed by specific educational programme and implemented by comparative feedback of individual doctor performance	Crossover	++	–
Cohen <i>et al</i> 1985 <sup>71</sup>	US ambulatory care	13 Preventive tasks	No	Local guidelines distributed by mail, residents received credit at university book shop after reading guidelines	BIB	"Modest" improvement in compliance	–
Tierney <i>et al</i> 1986 <sup>72</sup>	US ambulatory care	11 Preventive tasks	No	Local guidelines distributed by internal mail and implemented by: (i) computer generated reminder within consultation (ii) patient specific computer generated feedback	BIB	(i) ++ (ii) +	–
Cheney and Ramsdell 1987 <sup>73</sup>	US ambulatory care	12 Preventive tasks	No	National guidelines implemented by age-sex specific checklist placed in patient's notes	RCT-Dr	++	–
Cohen <i>et al</i> 1987, 1989 <sup>74 75</sup>	US ambulatory care	Smoking cessation	No	National guidelines distributed by specific educational programme and implemented by: (i) patient specific reminders (ii) nicotine gum (iii) (i) + (ii)	RCT-Dr	(i) ++++ (ii) ++++ (iii) +++++	–

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Wilson <i>et al</i> 1988 <sup>76</sup>	Canadian family practice	Smoking cessation	No	National guidelines: (i) implemented by nicotine gum (ii) distributed by specific educational intervention and implemented with nicotine gum	RCT-Dr	(i) +++++ (ii) +++++	(i) 0 (ii) +
Cummings <i>et al</i> 1989 <sup>77</sup>	US ambulatory care	Smoking cessation	No	National guidelines distributed by specific educational programme and implemented with reminders	RCT-Dr	++	+
McPhee <i>et al</i> 1989 <sup>78</sup>	US ambulatory care	7 Preventive tasks	No	National guidelines implemented by: (i) audit and feedback (ii) cancer screening reminders (iii) patient education	RCT-Dr	(i) + (ii) ++ (iii) ++	—
Turner <i>et al</i> 1990 <sup>79</sup>	US ambulatory care	6 Preventive tasks	No	National guidelines implemented by computer generated reminder (control group). In addition study group patients received reminders	RCT-Dr	++	—
McPhee <i>et al</i> 1991 <sup>80</sup>	US family practice	11 Preventive tasks	No	National guidelines implemented by computer generated reminders	RCT-Dr	++	—
Ornstein <i>et al</i> 1991 <sup>81</sup>	US ambulatory care	5 Preventive tasks	No	National guidelines distributed by intensive educational intervention and implemented by: (i) physician computer generated reminder (ii) patient reminder (iii) (i) + (ii)	RCT-Dr	(i) + (ii) + (iii) +	—
Cowan <i>et al</i> 1992 <sup>82</sup>	US ambulatory care	7 Preventive care tasks	No	National guidelines placed in patients' notes	RCT-Dr	+	—
Dietrich <i>et al</i> 1992 <sup>83</sup>	US ambulatory care	10 Preventive tasks	No	National guidelines: (i) distributed by specific educational intervention (ii) implemented by practice facilitator (iii) (i) + (ii)	RCT-Dr	(i) ++ (ii) ++ (iii) ++	—
Headrick <i>et al</i> 1992 <sup>84</sup>	US ambulatory care	Cholesterol	No	National guidelines distributed by lecture and implemented by: (i) guidelines placed in notes (ii) patient specific computer generated prompts	RCT-Dr	(i) + (ii) +	—
Litzelman <i>et al</i> 1993 <sup>85</sup>	US ambulatory care	3 Preventive tasks	No	National guidelines modified locally and implemented by requiring physicians to respond to computer generated reminders	RCT-Dr	+	—
Mayefsky and Foye 1993 <sup>86</sup>	US ambulatory care	Well child care	No	National guidelines implemented by individual physician feedback	RCT-Dr	++	—
<i>Grade II evidence: randomised controlled trial randomising patients, and before and after studies controlled by activity not targeted by guidelines</i>							
Morgan <i>et al</i> 1978 <sup>88</sup>	US hospital care	Antenatal care	No	National guidelines discussed locally and implemented by computer generated reminders	RCT-Pt	++	—
Rodney <i>et al</i> 1983 <sup>87</sup>	US family practice	2 Adult immunisations	No	Local guidelines distributed by educational programme and implemented by redesign of medical record to encourage two adult immunisations	CBA-A	++	—
McDowell <i>et al</i> 1986 <sup>88</sup>	Canadian family practice	Influenza vaccination	No	National guidelines implemented by: (i) computer generated reminder to the doctor (ii) telephone reminder to the patient (iii) reminder letter to patient	RCT-Pt	(i) ++ (ii) +++ (iii) +++	—
Prislin <i>et al</i> 1986 <sup>89</sup>	US family practice	2 Preventive tasks	No	Local guidelines distributed by specific educational conference and implemented by flowsheet placed in patients' notes	RCT-Pt	++++	—
Becker <i>et al</i> 1989 <sup>90</sup>	US ambulatory care	9 Preventive tasks	No	National guidelines implemented by: (i) reminder to physician (ii) reminders to physician and patient	RCT-Pt	(i) + (ii) ++	—
Chambers <i>et al</i> 1989 <sup>91</sup>	US family medicine	Mammography	No	National guidelines implemented by computer generated reminders	RCT-Pt	++	—
McDowell <i>et al</i> 1989 <sup>92</sup>	Canadian family practice	Blood pressure screening	No	National guidelines implemented by: (i) computer generated reminder to the doctor (ii) telephone reminder to the patient (iii) reminder letter to patient	RCT-Pt	(i) + (ii) + (iii) ++	—
McDowell <i>et al</i> 1989 <sup>93</sup>	Canadian family practice	Cervical screening	No	National guidelines implemented by: (i) computer generated reminder to the doctor (ii) telephone reminder to the patient (iii) reminder letter to patient	RCT-Pt	(i) 0 (ii) +++ (iii) +++	—

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Rosser <i>et al</i> 1991 <sup>94</sup>	Canadian family practice	Smoking cessation	No	National guidelines implemented by: (i) computer generated reminder to the doctor (ii) telephone reminder to the patient (iii) reminder letter to patient	RCT-Pt	(i) +++ (ii) +++++ (iii) +++++	-
Lilford <i>et al</i> 1992 <sup>95</sup>	UK hospital care	Antenatal care	Yes	Local guidelines implemented by: (i) structured paper record (ii) interactive computerised questionnaire	RCT-Pt	(i) + (ii) +	-
Rosser <i>et al</i> 1992 <sup>96</sup>	Canadian family practice	Tetanus vaccination	No	National guidelines implemented by: (i) computer generated reminder to the doctor (ii) telephone reminder to the patient (iii) reminder letter to patient	RCT-Pt	(i) ++ (ii) ++ (iii) +++	-
<i>Grade III evidence: before and after studies controlled by site and time series analyses</i>							
Thompson <i>et al</i> 1983 <sup>33</sup>	US prepaid health plan	Investigations in "routine" physical examinations	Yes	Local guidelines distributed by intensive educational programme and implemented with feedback on performance	CBA-Dr	+++	-
Robie 1988 <sup>97</sup>	US ambulatory care	6 Preventive tasks	No	National guidelines distributed by lecture implemented by chart reminders	CBA-Dr	+++	-
Schreiner <i>et al</i> 1988 <sup>98</sup>	US ambulatory care	4 Preventive tasks	No	National guidelines implemented by patient specific reminders	CBA-Dr	+	-
Nattinger <i>et al</i> 1989 <sup>99</sup>	US ambulatory care	Mammography	No	National guidelines implemented by: (i) audit and feedback (ii) visit-based intervention (including patient reminder and completed request form)	CBA-Dr	(i) ++ (ii) ++	-
Tape and Campbell 1993 <sup>100</sup>	US ambulatory care	8 Preventive tasks	No	National guidelines distributed by continuing medical education and implemented by flowsheet in paper record (control group). In addition, study group received computer generated reminders.	CBA-Dr	+	-
<i>Studies of prescribing, laboratory and radiological investigations</i>							
<i>Grade I evidence: balanced incomplete block designs, randomised controlled trials randomising doctors, and crossover trials</i>							
Marton <i>et al</i> 1985 <sup>101</sup>	US ambulatory care	Biochemistry and drug monitoring investigations	No	Local guidelines: (i) distributed by educational materials (ii) implemented by individual physician feedback (iii) (i) + (ii)	RCT-Dr	(i) 0 (ii) 0 (iii) +++++	-
Chassin and McCue 1986 <sup>102</sup>	US hospital care	Pelvimetry in pregnancy	Yes	Local guidelines distributed by educational meetings and mailed educational materials	RCT-Dr	+++	-
Landgren <i>et al</i> 1988 <sup>30</sup>	Australian hospital care	Antibiotic prophylaxis in surgery	No	Local guidelines distributed by anti-advertising campaign and implemented with aggregated feedback of baseline compliance	Crossover	+++	-
Avorn <i>et al</i> 1992 <sup>103</sup>	US residential care	Psychoactive drugs	No	Local guidelines distributed by lectures to non-medical staff, educational materials to all doctors, and educational outreach visits to high prescribing doctors	RCT-Dr	++++	-
Bearcroft <i>et al</i> 1994 <sup>104</sup>	UK general practice	Chest x ray examination	No	Local guidelines distributed by post	RCT-Dr	+	-
Oakeshott <i>et al</i> 1994 <sup>105</sup>	UK general practice	4 x ray investigations	No	National guidelines distributed by local department	RCT-Dr	++++	-
<i>Grade II evidence: randomised controlled trial randomising patients, and before and after studies controlled by activity not targeted by guidelines</i>							
Eisenberg <i>et al</i> 1977 <sup>106</sup>	US hospital care	Biochemistry investigations	No	Local guidelines implemented by physician specific feedback about over utilisation	CBA-A	0	-
De Vos Meiring and Wells 1990 <sup>31</sup>	UK general practice	9 Radiological investigations	No	Local guidelines distributed by mailing to targeted clinicians, no further attempt at implementation	CBA-A	+++	-
<i>Grade III evidence: before and after studies controlled by site and time series analyses</i>							
Brook and Williams 1976 <sup>107</sup> Lohr and Brook 1980 <sup>108</sup>	US ambulatory care	Injectable antibiotic prescribing	No	State guidelines distributed by targeted mailing and practice visits and implemented with financial incentives (payment was denied unless care complied with guidelines)	TSA	++++	-
Wong <i>et al</i> 1983 <sup>109</sup>	US hospital care	Biochemistry investigations	Yes	Local guidelines: (i) distributed by mailed educational materials (ii) (i) and implemented by change in request form	TSA	(i) 0 (ii) +++++	-
Fowkes <i>et al</i> 1984 <sup>110</sup>	UK accident and emergency care	Skull x ray examinations for patients with head injuries	No	National guidelines distributed by specific educational programme, implemented by structured head injury card	TSA	++++	-

Authors	Setting	Clinical area	End user involvement in guideline development?	Interventions to promote use of guidelines	Design of trial or study	Effect on process	Effect on outcome
Novich <i>et al</i> 1985 <sup>111</sup>	US hospital care	Biochemistry investigations	No	Local guidelines implemented by: (i) requirement for general justification for test (ii) requirement for specific justification for test	TSA	(i) ++++ (ii) +++++	–
Fowkes <i>et al</i> 1986 <sup>112</sup>	UK hospital care	Biochemistry and haematology investigations	No	Local guidelines distributed by specific educational meeting and implemented by weekly feedback	TSA	++++	–
Fowkes <i>et al</i> 1986 <sup>113</sup>	UK hospital care	Preoperative chest x ray examinations	No	National guidelines implemented by: (i) utilisation review committee (ii) feedback on individual compliance (iii) structured chest x ray request form (iv) review of requests by radiographer	CBA-Dr	(i) ++ (ii) ++ (iii) + (iv) ++	–
Ray <i>et al</i> 1986 <sup>114</sup>	US outpatient practice	Diazepam prescribing	No	State guidelines distributed by educational outreach visit	CBA-Dr	++	–
Avorn <i>et al</i> 1988 <sup>115</sup>	US hospital care	Dosage of intravenous antibiotics	Yes	Local guidelines distributed by lecture and printed materials, in advertisements and posters, implemented through a structured ordering form	TSA	++++	–
Bareford and Hayling 1990 <sup>116</sup>	UK hospital care	Haematological tests	No	Local guidelines distributed by specific educational programme and implemented by aggregated feedback and cancellation of inappropriate expensive tests	TSA	+++	–
Clarke and Adams 1990 <sup>117</sup>	UK accident and emergency care	Skull x ray requests in patients with head injuries	No	Local guidelines distributed by specific educational programme, implemented by general reminders	TSA	+++	–
Everitt <i>et al</i> 1990 <sup>118</sup>	US obstetric care	Prophylactic antibiotics for complicated caesarean section	No	Local guidelines approved by senior medical staff, distributed by pamphlet and departmental meetings, and implemented through a structured ordering form	TSA	+++++	–
Raisch <i>et al</i> 1990 <sup>119</sup>	US health maintenance organisation	Anti-ulcer treatment	No	Local guidelines distributed by educational outreach visit	CBA-Dr	0	–
Gama <i>et al</i> 1992 <sup>120</sup>	UK hospital care	Cardiac enzymes	No	Local guidelines distributed by specific educational programme	TSA	++++	–
Soumerai <i>et al</i> 1993 <sup>121</sup>	US hospital care	Antibiotics	No	Local guidelines implemented with a structured ordering form	TSA	+	–

Designs of trial or study: BIB balanced incomplete block design; PBIB partially balanced incomplete block design; RCT-Dr trial randomised by individual doctor, team, unit, or hospital; RCT-Pt trial randomised by patient; CBA-A before and after study controlled by untargeted activity; CBA-Dr before and after study controlled by other doctors; TSA time series analysis.

Effect sizes (average effect size of significant results): – not measured; 0 no significant effect; + absolute effect between 0–9%; ++ absolute effect between 10–19%; +++ absolute effect between 20–29%; ++++ absolute effect between 30–39%; +++++ absolute effect >39%.

clinical settings and tasks.<sup>28–121</sup> They comprised 35 studies of clinical care, 34 of preventive care, and 22 of prescribing or the use of radiological or laboratory investigations. Only 14 studies were based in the United Kingdom, including four studies of clinical care (common paediatric conditions,<sup>50</sup> infertility management and referral,<sup>51</sup> dyspepsia,<sup>52</sup> and hypertension<sup>61</sup>), one study of preventive care (antenatal care<sup>65</sup>), and nine studies of investigations (of which six were radiological).<sup>31 104 105 110 112 113 116 120</sup>

Of the 87 studies which examined effects on the process of care, as measured by adherence to recommendations of practice guidelines, 81 reported significant improvements. Twelve of the 17 studies which assessed patient outcome reported significant improvements. All 14 studies based in the United Kingdom noted significant improvements in compliance with guidelines; the only United Kingdom study to measure patient outcome also reported significant improvement.<sup>50</sup> The evidence from those studies considered to provide the most reliable evidence confirmed these findings: 43 out of 44 grade I studies reported significant changes in process and eight out of 11 showed significant changes in outcome. The evidence from these rigorous evaluations strongly

suggests that properly developed guidelines can change clinical practice and may lead to changes in patient outcome.

### Introducing guidelines into practice

Although guidelines can be used to help to change clinical practice, their adoption and use is not automatic and will depend to a great extent on how they are developed and implemented. The behavioural factors which influence adherence with guidelines are very complex. For example, it is often assumed that guidelines developed by the clinicians who will ultimately use them (end users) improves their implementation, owing partly to a perception of increased ownership. However only two<sup>41 50</sup> of the four studies identified<sup>39 41 46 50</sup> supported this. Guidelines produced locally by professional end users may at times be seen as less credible than those produced by locally respected clinicians (opinion leaders) or national experts.<sup>39</sup> Some interventions based on the passive receipt of information (for example, publication in professional journals and mailing to relevant groups) influence professionals' awareness<sup>32</sup> and knowledge of guidelines.<sup>64</sup> Three studies in the United Kingdom of local general practitioners' guidelines for radiological investigations found

improved compliance after targeted mailing without any supporting implementation strategy.<sup>31 104 105</sup> However, these approaches are usually insufficient to change professional behaviour.

Educational interventions, requiring more active participation by professionals (including targeted seminars, educational outreach visits, and the involvement of opinion leaders) are more likely to lead to changes in behaviour. There is some evidence of the effectiveness of educational outreach visits by trained staff meeting professionals in their practice settings in influencing prescribing behaviour (for example, Avorn *et al*<sup>103</sup>) and of the role of opinion leaders (professionals identified by their colleagues as influential).<sup>48</sup> Because these interventions require the investment of valuable resources rigorous evaluation of their cost effectiveness is important before their widespread use.

Implementation strategies are more likely to be effective when they operate directly on the consultation between the professional and the patient. Such strategies include restructuring medical records (for example, Emslie *et al*,<sup>51</sup> Cheney and Ramsdell,<sup>73</sup> Rodney *et al*<sup>87</sup>), patient specific reminders during the consultation (for example, McDonald *et al*<sup>68 69</sup>) and patient mediated interventions (for example, McPhee *et al*<sup>78</sup>) (whose aim is to affect professional practice through informing patients). Strategies operating outside the consultation that have been rigorously evaluated include patient specific feedback (for example, Tierney *et al*<sup>72</sup>) and aggregated feedback on compliance with guidelines (for example, Durand-Zaleski *et al*<sup>65</sup>), financial incentives,<sup>107 108</sup> explicit marketing,<sup>30</sup> and professional peer review.<sup>113</sup>

Several studies compared different educational and implementation strategies (table).<sup>44 45 47 48 54 57 72 74 76 78 81 83 84 88 90 92-96 99 101 109 111 113</sup> This research suggests that educational interventions requiring active professional participation and implementation strategies that are closely related to clinical decision making are more likely to lead to successful implementation. In other words, implementation strategies which are nearer the end user and integrated into the process of healthcare delivery are more likely to be effective. However, insufficient evidence exists to reach firm conclusions about the relative effectiveness of different educational and implementation strategies in different contexts.

### **Desirable attributes of clinical practice guidelines**

Strong evidence exists that well implemented clinical guidelines can be used to change the process and outcome of care. However, this is only potentially worthwhile if the changes result in improved quality of care and efficient use of resources. Guidelines are referred to as *valid* if, when followed, they lead to improvement in patient outcome at acceptable costs. Validity depends on how well evidence is identified, synthesised, and incorporated

into the guideline and, therefore, on how and by whom the guideline is developed.<sup>122</sup>

### **AVOIDING BIAS**

Guidelines are commonly developed by "expert" panels uninformed by the results of formal systematic literature reviews of the research evidence. This approach relies too heavily on panel members' opinions and knowledge of published work. Unfortunately, published expert recommendations often lag behind available evidence<sup>123</sup> and may reflect individual enthusiasms rather than the knowledge base. Such bias may be overcome if those developing guidelines adopt a systematic approach to identifying and synthesising evidence.<sup>124</sup> Guidelines based on reviews that identify, synthesise, and interpret evidence systematically are, therefore, more likely to be valid. Since local groups may lack the resource and skills needed to develop evidence based guidelines<sup>125</sup> care must be taken to ensure that any increased acceptability owing to local development of guidelines is not achieved at the expense of their potential to improve patient outcomes.

Many methods can be used to translate evidence into practice recommendations, including peer groups, nominal groups, Delphi techniques, and consensus conferences.<sup>126-7</sup> All have potential biases and there is little evidence on their relative merits.

### **CONSIDERING COST EFFECTIVENESS**

Practice guidelines should not be solely concerned with clinical effectiveness but should also pay regard to the costs of treatments if they are to maximise improvements in health status.<sup>6 128-130</sup> They should explicitly take into account the costs of interventions so that the limited resources available are used efficiently; guidelines that ignore the issue of cost effectiveness might recommend practices resulting in large increases in cost for little corresponding improvement in health. Unfortunately, development of guidelines has largely ignored the issue of costs. Since costs of treatments may vary across sites the local development of guidelines will need to consider local factors which may influence cost effectiveness.

### **INDICATING THE EVIDENCE BASE**

Guidelines should clearly indicate the basis of each recommendation and the degree to which it is supported by good research evidence. The target patient population and circumstances under which the recommendations apply also should be clearly stated. Clarity of definitions, language, and format is also essential. Unfortunately, few published guidelines give enough details about development for their validity to be confidently assessed.<sup>131</sup> Those developing guidelines should provide enough information to allow potential users to make an informed judgment about validity and relevance to specific circumstances.<sup>132</sup> A guide for structured guideline abstracts, encouraging the publication of details of development is now available.<sup>133</sup>

## MAINTAINING VALIDITY

Those developing guidelines should specify how their guidelines should be monitored to identify major changes in knowledge and how the guidelines should be routinely reviewed to incorporate new knowledge. Guidelines should also be piloted in several sites to ensure their applicability and relevance, and the experience of patients as well as professional users should be taken into account.

**Guidelines and commissioning**

The evidence discussed in the previous sections shows that properly developed, evidence based guidelines accompanied by an effective implementation strategy can help promote cost effective health care. Therefore clinical practice guidelines may be a useful focus for healthcare commissioning.

The purchaser's role in this process may involve identifying the best evidence of effectiveness and cost effectiveness or valid national guidelines and prioritising areas for introducing local guidelines. Purchasers also have a role in sponsoring the development of local guidelines, incorporating them in contracts and service specifications, and supporting providers in implementing them. By itself, however, commissioning is unlikely to be sufficient to implement guidelines. Purchasers also have a role in monitoring and evaluating the development and implementation of local guidelines. This may include some form of review of utilisation<sup>6</sup> or audit to measure the extent to which recommended standards are actually achieved. Purchasers and providers need to agree on criteria for reviewing practice based on guidelines. Ideally, relevant data on patient outcomes should be collected and analysed routinely to explore how implementation of guidelines may be influencing quality of care.

A limited number of guidelines can be assimilated by healthcare professionals or provider organisations at any one time. Local activities should be coordinated to prioritise the guidelines that professional groups are asked to implement. Greater priority should be given to introducing guidelines which address important local need, where rigorous national guidelines or research evidence are readily available, and where current practice diverges from best practice, thus indicating the potential for significant gains in health. Local development of guidelines should be both adequately resourced and multidisciplinary (including representatives of all key clinical disciplines and providers and purchasers) as successfully implementing guidelines normally requires changes in the behaviour of more than one professional group.<sup>134 135</sup> Public involvement in developing guidelines may enhance implementation, especially when public expectations influence practice. Clinical audit groups may be well placed to coordinate and resource the development of local guidelines if encouraged to develop skills in leading and facilitating local groups developing guidelines.

Clinicians' concerns about the legal status of guidelines and potential litigation resulting

from non-compliance may be a major barrier to implementing guidelines. However, compliance with, or deviation from, a clinical guideline is unlikely to prove conclusive in a medical negligence action, unless it can be shown that the guideline is so well established that no responsible doctor acting with reasonable skill would fail to comply with it. Therefore, medicolegal issues do not, in principle, represent a barrier to implementation.<sup>136</sup>

**Research issues**

Guidelines are not always the most appropriate tool to promote cost effective health care. It would be useful to study the optimal contribution that guidelines can make. Research is needed to identify the most cost effective methods for developing valid and reliable guidelines, which should include research into methods for deriving recommendations and incorporating costs. It is also important to develop valid instruments for critically appraising guidelines.<sup>131</sup> Research is required of the effects of different formats and styles of guidelines on their adoption and of barriers to adopting guidelines. Although some evidence exists on the effectiveness of different educational and implementation strategies these are still poorly understood in the United Kingdom. Future research will be able to build on the reviews from the new Cochrane Collaboration on Effective Professional Practice, which will provide up to date systematic reviews of the evidence on the effectiveness of different approaches to implementation.<sup>137</sup>

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